OCT 1 5 2001

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

Submitter's Name: Toray Industries (America), Inc.
600 Third Avenue, 5th floor
New York, NY 10016-1902
Telephone: (212) 697-8150
Contact person: Mr. Hidehiko Okubo, Director, Medical and Pharmaceutical

Date of Summary: August 14, 2000

Device Name: Toraysulfone™ Dialyzer

Device Classification Name: High permeability hemodialysis system (78 KDI); 21 CFR, Part 876.5860

Legally Marketed Device to which Equivalence is Claimed: The legally marketed predicate device is the Fresenius Inc. Hemoflow Hollow Fiber Dialyzer (K921134), determined to be substantially equivalent to a legally marketed (preAmendment) device on December 2, 1993.

Device Description: The Toraysulfone dialyzer consists of highly permeable polysulfone hollow fibers housed in a polystyrene casing and secured at each end with polystyrene headers. High permeability dialyzers must be used only in conjunction with dialysis machines equipped with an ultrafiltration controller. The Toraysulfone dialyzer is provided in a range of sizes based on the surface area of the hollow fiber membrane. The device is gamma-ray sterilized and intended for single use only.

Intended Use: The Toraysulfone dialyzer is indicated for use in hemodialysis treatment of patients with acute or chronic renal failure.

Descriptive Summary of Technological Characteristics and Those of Predicate Device: The material of the membrane (hollow fiber) and membrane surface area of the Toraysulfone dialyzer are identical to those of the Fresenius Hemoflow dialyzer. The features and capabilities of the predicate and proposed devices are identical; they also have similar flow and clearance data.

Performance Data:
Bench Testing: Testing was conducted on the Toraysulfone dialyzer in accordance with the FDA guidance. All samples met the acceptance criteria. The test results establish that the Toraysulfone dialyzer possesses performance characteristics that make it acceptable for its intended use.

Clinical Testing: The Toraysulfone dialyzer was evaluated as a single-use dialyzer in the clinical setting at two sites in Japan. The device performed successfully in all 322 uses in chronic dialysis patients. It was judged to be effective in at least 82% of all cases. There were 54 adverse events reported. Thirty-five of these were judged as related to the device; all were related to the presence of residual blood in the dialyzer and were categorized as "minor".

Conclusion: The information and data provided in this 510(k) Notification establish that the Toraysulfone dialyzer is substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 5 2001

Toray Industries (America), Inc.
c/o Lisa S. Jones, RAC
Regulatory Affairs Consultant
Devices for the Future
540 College Street
Bellaire, Texas 77401

Re: K002512
Trade/Device Name: Toraysulfone™ Dialyzer
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: 78 KDI
Dated: August 6, 2001
Received: August 7, 2001

Dear Ms. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K002512

Device Name: Toraysulfone™ Dialyzer

Indications for Use: The Toraysulfone dialyzer is indicated for use in hemodialysis treatment of patients with acute or chronic renal failure.

(Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use ____
(Per 21 CFR 801.109)

David G. Kaysen

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K002512